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JC891 U.S. PTO

**UTILITY PATENT APPLICATION TRANSMITTAL**  
**(Small Entity)***(Only for new nonprovisional applications under 37 CFR 1.53(b))*

Docket No.

B-29

Total Pages in this Submission  
sheets

156

**TO THE ASSISTANT COMMISSIONER FOR PATENTS****Box Patent Application****Washington, D.C. 20231**

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

**Methods and compositions for immunotherapy of B cell involvement in promotion of a disease condition comprising multiple sclerosis**

and invented by:

**Emilio Barbera-Guillem**  
**M. Bud Nelson**If a **CONTINUATION APPLICATION**, check appropriate box and supply the requisite information:☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: \_\_\_\_\_

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: \_\_\_\_\_

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: \_\_\_\_\_

Enclosed are:

**Application Elements**

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 36 pages and including the following:
  - a. ☒ Descriptive Title of the Invention
  - b. ☒ Cross References to Related Applications *(if applicable)*
  - c. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
  - d. ☐ Reference to Microfiche Appendix *(if applicable)*
  - e. ☒ Background of the Invention
  - f. ☒ Brief Summary of the Invention
  - g. ☒ Brief Description of the Drawings *(if drawings filed)*
  - h. ☒ Detailed Description
  - i. ☒ Claim(s) as Classified Below
  - j. ☒ Abstract of the Disclosure

JC873 U.S. PTO  
09/643595

08/22/00

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## Application Elements (Continued)

3. ☒ Drawing(s) (when necessary as prescribed by 35 USC 113)
- a. ☒ Formal      b. ☐ Informal      Number of Sheets 1 (one)
4. ☒ Oath or Declaration
- a. ☒ Newly executed (original or copy)      ☐ Unexecuted
- b. ☐ Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional application only)
- c. ☒ With Power of Attorney      ☐ Without Power of Attorney
- d. ☐ DELETION OF INVENTOR(S)  
Signed statement attached deleting inventor(s) named in the prior application,  
see 37 C.F.R. 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation By Reference (usable if Box 4b is checked)  
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. ☐ Computer Program in Microfiche
7. ☐ Genetic Sequence Submission (if applicable, all must be included)
- a. ☐ Paper Copy
- b. ☐ Computer Readable Copy
- c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

## Accompanying Application Parts

8. ☒ Assignment Papers (cover sheet & documents)
9. ☐ 37 CFR 3.73(b) Statement (when there is an assignee)
10. ☐ English Translation Document (if applicable)
11. ☒ Information Disclosure Statement/PTO-1449      ☒ Copies of IDS Citations
12. ☐ Preliminary Amendment
13. ☒ Acknowledgment postcard
14. ☒ Certificate of Mailing
- ☐ First Class      ☒ Express Mail (Specify Label No.): EL497108525US

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(Only for new nonprovisional applications under 37 CFR 1.53(b))

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## Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. ☒ Small Entity Statement(s) - Specify Number of Statements Submitted: 1 (one)
17. ☐ Additional Enclosures (please identify below):

## Fee Calculation and Transmittal

### CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	17	- 20 =	0	x \$9.00	\$0.00
Indep. Claims	4	- 3 =	1	x \$39.00	\$39.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
BASIC FEE					\$345.00
OTHER FEE (specify purpose) <u>assignment recordal fee : \$40</u>					\$40.00
TOTAL FILING FEE					\$424.00

- ☒ A check in the amount of **\$424.00** to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. **500438** as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of \_\_\_\_\_ as filing fee.
- ☒ Credit any overpayment.
- ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: 22 August 2000

  
Signature

M. Bud Nelson  
Reg. No. 35,300

cc:

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL BUSINESS  
STATUS (37 CFR 1.9(f) AND 1.27 (c)) - SMALL BUSINESS CONCERN**

Docket No.  
B-29

Serial No.

Filing Date

22 August 2000

Patent No.

Issue Date

Applicant/ **Emilio Barbera-Guillem and M. Bud Nelson**  
Patentee:

Invention: **Methods and compositions for immunotherapy of B cell involvement in promotion of a disease condition comprising multiple sclerosis**

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:
- ☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: **BioCrystal Ltd.**ADDRESS OF CONCERN: **575 McCorkle Boulevard, Westerville, Ohio, 43082-8888**

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above identified invention described in:

- ☒ the specification filed herewith with title as listed above.
- ☐ the application identified above.
- ☐ the patent identified above.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed on the next page and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such person, concern or organization exists.  
☐ each such person, concern or organization is listed below.

FULL NAME

ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME

ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME

ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME

ADDRESS

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: John M. Swartz, Ph.D.

TITLE OF PERSON SIGNING

OTHER THAN OWNER: CEO

ADDRESS OF PERSON SIGNING: BioCrystal Ltd.  
575 McCorkle Boulevard  
Westerville, Ohio, 43082-8888

SIGNATURE:



DATE: 21 August 2000

**CERTIFICATE OF MAILING "EXPRESS MAIL" (37 CFR 1.10)**

Docket No.

B-29

Applicant(s):

Serial No.

Filing Date

22 August 2000

Examiner

Group Art Unit

Invention: **Methods and compositions for immunotherapy of B cell involvement in promotion of a disease condition comprising multiple sclerosis**

I hereby certify that the following correspondence:

patent application

(Identify type of correspondence)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Assistant Commissioner for Patents, Washington, D.C. 20231 on

22 August 2000

(Date)

M. Bud Nelson

(Typed or Printed Name of Person Mailing Correspondence)

  
(Signature of Person Mailing Correspondence)EL497108525US

("Express Mail" Mailing Label Number)

**Note: Each paper must have its own certificate of mailing.**

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08/22/00